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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
09/465,054	12/16/1999		DAVID BURTON	990326.ORI	8408		
7	7590 12/02/2003				EXAMINER		
Aleya R Char	nplin E	sq	PATEL, MITAL B				
Fulbright & Jav	worski L	LP					
225 South Sixt	h Street	# 4850	ART UNIT	PAPER NUMBER			
Minneapolis, 1	MN 554	402-4320	3743				

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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			Application No.		Applicant(s)	Ĺ			
Office Action Summary			09/465,054		BURTON, DAVID				
			Examiner		Art Unit				
			Mital B. Patel	<u></u> .	3743				
Period fo	The MAILING DATE of this communication Reply	tion app	ars on the cover sheet w	∕ith the c	orrespondence addre	≯ SS			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status									
1)⊠	Responsive to communication(s) filed of	on <u>17 Se</u>	ptember 2003.						
• 2a)⊠	This action is FINAL . 2b)[☐ This a	ction is non-final.						
3)[3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.								
Disposit	ion of Claims								
5)□ 6)⊠ 7)□	Claim(s) 32 and 57-74 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. Claim(s) is/are allowed. Claim(s) 32,57-74 is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or election requirement.								
Applicat	ion Papers								
10)	The specification is objected to by the E The drawing(s) filed on is/are: a Applicant may not request that any objectio Replacement drawing sheet(s) including the The oath or declaration is objected to by)□ acce on to the d e correction	pted or b) objected to rawing(s) be held in abeya on is required if the drawin	ance. See g(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR				
Priority	under 35 U.S.C. §§ 119 and 120								
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78. a) The translation of the foreign language provisional application has been received. 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.									
	nt(s)ce of References Cited (PTO-892)		A) Interview	Summary	(PTO-413) Paper No(s).				
2) Notice	ce of References Cited (P10-692) ce of Draftsperson's Patent Drawing Review (PT0 mation Disclosure Statement(s) (PT0-1449) Pape		5) Notice of		Patent Application (PTO-1				

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DETAILED ACTION

Response to Amendment/Arguments

- 1. Applicant's arguments filed 9/17/03 have been fully considered but they are not persuasive.
- 2. Applicant's arguments with respect to claim 32 have been considered but are most in view of the new ground(s) of rejection.
- 3. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "claim 32 has been amended to reflect that the mask is a breathing mask that covers only the nasal region of the face...") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Please note that claim 32 recites that the mask is shaped to form a seal around the patient's nose **and mouth** which is not commensurate with "covers only the nasal region."

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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⁽b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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- 5. Claims 32, 57-62, 63, 65-67, 70, 71, 72, 73 and 74 rejected under 35 U.S.C. 102(b) as being anticipated by Tripp, Jr. et al. (H1039).
- 6. **As to claim 32**, Tripp teaches a breathing mask **106** for monitoring a patient during gas delivery comprising a body having an internal surface, an external surface, and a perimeter shaped to form a seal around the patient's nose and mouth; and at least one EEG (**See Col. 12**, **line 3**) sensor extended from the mask and positioned to detect brain activity.
- 7. **As to claim 57**, Tripp teaches a mask wherein the perimeter surface is adapted to detect muscle activity.
- 8. As to claim 58, Tripp teaches a mask wherein the perimeter surface is adapted to detect ECG (See Col. 5, lines 62-68).
- 9. **As to claim 59**, Tripp teaches a mask further comprising a flow sensor connected to the internal surface (**See Col. 6**, **lines 37-68**).
- 10. **As to claim 60**, Tripp teaches a mask further comprising an oxygen saturation sensor extended from the mask (**See Col. 5**, **lines 62-68**).
- 11. As to claim 61, Tripp teaches a mask wherein the perimeter surface is adapted to detect eye movements (See Col. 12, lines 1-6).
- 12. **As to claim 62**, Tripp teaches a mask **106** comprising a body having an internal surface, an external surface, a perimeter surface, and an air hose **126** extending from the body; and at least one EMG sensor connected to the body and positioned to detect muscle activity relating to a sleep state (**See Col. 12, lines 1-6**).

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- 13. **As to claim 63**, Tripp teaches a mask further comprising a first sensor **138,140** positioned on the internal surface for detecting nasal breathing and a second sensor **303,304** positioned on the external surface for oral breathing.
- 14. **As to claim 65**, Tripp teaches a mask further comprising at least one EEG sensor positioned on the perimeter surface (See Col. 12, lines 1-6).
- 15. **As to claim 66**, Tripp teaches a mask further comprising at least one EOG sensor positioned on the perimeter surface (**See Col. 12**, **lines 1-6**).
- 16. **As to claim 67**, Tripp teaches a mask wherein a portion of the perimeter surface is comprised of a conductive carbonized silicon rubber material (**See Col. 7**, **lines 48-57**).
- 17. **As to claim 70**, Tripp teaches a mask further comprising a microphone **136** coupled to the body.
- 18. **As to claim 71**, Tripp teaches a mask wherein the perimeter surface is adapted to sense air leaks (See Col. 11, lines 46-53).
- 19. **As to claim 72**, Tripp teaches a mask further comprising a patient recycled air detection system positioned on the internal surface (See Col. 11, 39-53).
- 20. As to claim 73, Tripp teaches a mask assembly comprising a mask 106; a plurality of sensors 132, 133, 138, 140, 210, 212, 226, 228 connected to the mask; and a computer (See Col. 3, lines 6-9) in communication with the sensors, the computer adapted to determine sleep state.
- 21. As to claim 74, Tripp teaches a mask assembly comprising a mask 106; a plurality of sensors 132, 133, 138, 140, 210, 212, 226, 228 connected to the mask; and

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a computer (See Col. 3, lines 6-9) in communication with the sensors, the computer adapted to determine arousal.

Claim Rejections - 35 USC § 103

- 22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 23. Claims 64 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tripp, Jr. et al (H1039) in view of Wiesmann et al (US 6,199,550).
- 24. **As to claim 64**, Tripp teaches essentially all of the limitations except for wherein the first and second sensors are thermal sensors. However, Wiesmann does teach the use of thermal sensors to detect the body temperature. Therefore, it would be obvious to one of ordinary skill in the art to provide thermal sensors as taught by Weismann in order to detect body temperature.
- 25. **As to claim 69**, Tripp teaches essentially all of the limitations except for a position sensor coupled to the body. However, Wiesmann does teach the use of a position sensor in order to create a map of the target in sight. Therefore, it would have been obvious to one of ordinary skill in the art to provide position sensors in the mask of Tripp so that a map of the target in sight can be created.
- 26. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tripp, Jr. et al (H1039) in view of Bertheau (US 5,503,147).

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27. **As to claim 68**, Tripp teaches essentially all of the limitations except for the straps having at least one sensor positioned thereon. However, Bertheau does teach sensors positioned on the strap in order to monitor the fit of the mask. Therefore, it would have been obvious to one of ordinary skill in the art to provide at least one sensor on the straps of Bertheau to indicate the fit of the mask.

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 703-306-5444. The examiner can normally be reached on Monday-Friday (8:00 - 4:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Aaron J. Lewis
Primary Examiner

mbp